

Notice of Allowability

Application No.

10/016,403

Examiner

David J. Steadman

Applicant(s)

HOLLADAY, LESLIE A.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 12/29/06.
2. ☒ The allowed claim(s) is/are 26 and 29-43.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 20070830
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Status of the Application

- [1] Claims 26 and 29-43 are pending in the application.
- [2] Applicant's amendment to the claims, filed on 12/29/06, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] In view of the claim amendment filed on 12/29/06, all rejections set forth in the Office action mailed on 11/8/06 are withdrawn.

Examiner's Amendment to the Claims

- [4] An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
- [5] Authorization for this examiner's amendment was given in a telephone interview with Ms. Jane E. Inglese on 3/12/07.
- [6] The application has been amended as follows:
 - (i) Please replace the second occurrence of ---a--- in lines 3 of claims 26 and 36 with ---the--- such that lines 3 of claims 26 and 36 read, "(a) preparing a synthetic analog of the parent human growth hormone".
 - (ii) Please replace ---anionic--- in lines 2 of claims 34 and 42 with ---anodic---
 - (iii) Please replace ---electrotransport--- in lines 3 of claims 34 and 42 with ---electrotransport---

Reasons for Allowance

[7] The following is an Examiner's statement of reasons for allowance. The method of claim 26 has been limited to the use of SEQ ID NO:8, except at least one Gln residue at position 16, 30, 31, or 36 is replaced with a His. The method of claim 36 has been limited to the use of SEQ ID NO:8, except at least two Gln residues at positions 16, 24, 30, 31, or 36 are replaced with His. While variants of human growth hormone releasing hormone are known in the prior art (see, e.g., Vale et al., US Patent 4,528,190; cited in a prior Office action), the examiner can find no teaching or suggestion in the prior art of record for a human growth hormone releasing hormone as encompassed by the claims. Therefore, the claimed invention, directed to methods of delivering the analogs of human growth hormone releasing hormone as noted above through a body surface by electrotransport, are allowable over the prior art of record.

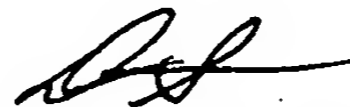
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656